



February 27, 2019

FUJIFILM Corporation
% Jeffrey Wan
Specialist, Regulatory Affairs
FUJIFILM Medical Systems U.S.A., Inc
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K183683
Trade/Device Name: FUJIFILM Double Balloon Endoscopes EN-580T, EC-450BI5, EN-450P5/20,
and EN-450T5
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDA, FDF
Dated: December 27, 2018
Received: December 28, 2018

Dear Jeffrey Wan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K183683

Device Name

FUJIFILM Double Balloon Endoscopes EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5

Indications for Use (Describe)

EN-580T, EN-450P5/20 and EN-450T5 are intended for the visualization of the upper and lower digestive tracts. Specifically, for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, duodenum, small intestine, large intestine, and rectum.

EC-450BI5 is intended for the optical visualization of the gastrointestinal tract. This includes the rectum, large and small intestines. It is intended for observation, diagnosis, and endoscopic treatment.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

FUJIFILM Double Balloon Endoscopes EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5

Date: December 27, 2018

Submitter's Information:

FUJIFILM Corporation
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FDA Establishment Registration Number: 3001722928

Contact Person:

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Specialist, Regulatory Affairs
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Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Double Balloon Endoscopes EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5
Common Name:	Enteroscope (EN-580T, EN-450P5/20, EN-450T5) Colonoscope (EC-450BI5)
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Classification:	Endoscope and accessories, 21 C.F.R. § 876.1500
Product Code:	FDA, FDF

Predicate Devices:

FUJIFILM Double Balloon Endoscope Model EN-580T (K143556)
Fujinon EC-450BI5 (K090116)
Fujinon EN-450P5/20 (K040048)

Intended Use / Indications for Use:

EN-580T, EN-450P5/20 and EN-450T5 are intended for the visualization of the upper and lower digestive tracts. Specifically, for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, duodenum, small intestine, large intestine, and rectum.

EC-450BI5 is intended for the optical visualization of the gastrointestinal tract. This includes the rectum, large and small intestines. It is intended for observation, diagnosis, and endoscopic treatment.

Device Description:

FUJIFILM Double Balloon Endoscopes EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 are comprised of three general sections: a control portion, an insertion portion and an umbilicus. The control portion controls the angulation of the endoscope. This portion also controls the flexibility of the distal end in the endoscope. The insertion portion contains glass fiber bundles, several channels and a complementary Charge-Coupled Device (CCD) image sensor in its distal end. The channels in the insertion portion assist in delivering air/suction as well as endoscope accessories, such as forceps. The glass fiber bundles allow light to travel through the endoscope and emit light from the tip of the insertion portion to illuminate the body cavity. This provides enough light to the CCD image sensor to capture an image and display it on the monitor. The umbilicus consists of electronic components needed to operate the endoscope when plugged in to the video processor and the light source. The endoscope is used in combination with FUJIFILM's video processors, light sources and peripheral devices such as monitor, printer, foot switch, and cart.

Technological Characteristics:

The proposed devices EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 differ from the predicate devices in the following minor modifications:

- Compatibility with different components and accessories
- Expansion of transport and storage conditions to a temperature range of -20°C to 60°C and a humidity range of 10 to 85% RH.
- Use of a new epoxy resin in the manufacturing process. Both the new and original epoxy resins can be used for repair.
- Removal of the option to inflate a balloon by manual syringe.
- Design specification changes (EN-450T5 only)

Performance Data:

Electrical safety of the proposed devices were evaluated using the following standards: ANSI/AAMI ES 60601-1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

The proposed devices EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 were adopted into biocompatibility testing conducted on the predicate devices EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 using the following consensus standards: ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

The proposed devices EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 were adopted into the reprocessing validation of the predicate devices using the following consensus standards: AAMI TIR12:2010, AAMI TIR30:2011. Validation of the cleaning, disinfection, and sterilization instructions was performed in accordance with FDA's guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," published March 17, 2015.

Fujifilm conducted the following performance testing on the proposed devices EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 to ensure that the modified devices perform equivalently to the predicate devices:

- Field of view
- Bending capability
- Rate of air supply
- Rate of water supply
- Suction rate
- Working length
- Forceps channel diameter
- Viewing direction
- Resolution
- LG output

In all cases, the devices met the pre-defined acceptance criteria for the test.

Substantial Equivalence:

The company's EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 have the same intended use and indications for use as the previously cleared predicates EN-580T(K143556), EC-450BI5 (K090116), and EN-450P5/20 (K040048). In addition, the proposed devices have similar technological characteristics and principles of operation as the predicates. The minor differences between the proposed devices and their predicate devices do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed devices EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 are substantially equivalent to their predicate devices.

Conclusions:

The modified EN-580T, EC-450BI5, EN-450P5/20, and EN-450T5 are substantially equivalent to the predicate EN-580T, EC-450BI5, and EN-450P5/20 and conform to applicable medical device safety and performance standards.